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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,816	10/19/2005	Lydie Bougueleret	4-33636A/GEP	7751

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,816	BOUGUELERET ET AL.	
	Examiner	Art Unit	
	JACOB CHEU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 9-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Applicant's amendment filed on 9/4/2008 has been received and entered into record and considered.
The following information provided in the amendment affects the instant application:

1. Claims 1-20 are pending.

2. Currently, claim 8 is under examination. Claims 1-7 and 9-20 are withdrawn from further consideration.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagita (I) (US 6852692) in view of Kimberly et al. (US 5985561).

Yanagita et al. teach an isolated polypeptide as a therapeutic composition to ameliorate urination disorder (See Abstract). The therapeutic polypeptide taught by Yanagita (SEQ ID No. 2) has the same amino acid sequence as the recited *SEQ ID No. 1*. Yanagita et al. also teach using recombinant DNA technique for producing said polypeptide for further analysis (Col. 5, line 65- Col. 6, line 10). However, Yanagita et al. do not explicitly teach fusing the SEQ ID No. 2 with a polypeptide IgG Fc.

Kimberly et al. teach coupling polypeptide to IgG Fc portion in order to prolong the in vivo half-life of the therapeutic agents (Col. 11, line 32-40). .

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention was made to have motivated Yanagita et al. to couple the polypeptide therapeutic agent with IgG Fc protein to improve the effectiveness of the treatment. One ordinary artisan in the field would have been coupled the polypeptide with IgG Fc in order to take the advantage of prolonging the life of the therapeutic agents within the body for longer and more effective combating the target disease.

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bridon et al. (WO 200069900) in view of Goodwin et al. (US 5674704).

Bridon et al. teach an isolated polypeptide, i.e. SEQ ID No. 939 which has the same amino acid sequence as the recited SEQ ID No. 3. Note, the recited language uses an open term "comprising". The SEQ ID No. 939 in Bridon et al. reference has 48 amino acid residues encompassing the recited *SEQ ID No. 5* which has 13 amino acid residues. Bridon et al. also teach using recombinant DNA technique for producing said polypeptide

for further analysis (Col. 5, line 65- Col. 6, line 10). However, Bridon et al. do not explicitly teach fusing the SEQ ID No. 3 with a IgG Fc polypeptide.

Goodwin et al. teach coupling the target polypeptide with IgG Fc for a better yield in the process of isolation by using protein A/or G affinity column (See Example 1; Col. 17, line 23-40). It has been well-established that the IgG Fc has a higher affinity for protein A/or G and it has been widely used in the field to use IgG Fc for isolation purpose.

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention was made to have motivated to Bridon et al. to couple the polypeptide with IgG Fc such as taught by Goodwin et al. to enhance isolation efficiency. One ordinary artisan in the field would have been motivated to couple the target peptides with IgG Fc in order to take the advantage of higher affinity of IgG Fc with protein A/or G for a better yield in isolation of the target peptides.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagita (II) (US 20070161555) in view of Layton et al..

Yanagita et al. teach a therapeutic composition comprising isolated polypeptide (i.e. SEQ ID No. 2 which has the same amino acid sequence as the recited *SEQ ID No. 2*) for inhibiting spontaneous myometrial contraction or bradykinin-induced contraction in premature pregnancy (See Abstract; Secion 0002 and 0033). Note, the recited language uses an open term "comprising". The SEQ ID No. 2 in Yanagita et al. reference has 185 amino acid residues encompassing the recited SEQ ID No. 2 containing 164 amino acid residues. Yanagita et al. also teach using recombinant DNA technique for producing said polypeptide for further analysis (Col. 5, line 65- Col. 6, line 10). However, Yanagita et al. do not explicitly teach fusing the SEQ ID No. 2 with a IgG Fc polypeptide.

As discussed above, Kimberly et al. teach coupling polypeptide to IgG Fc portion in order to prolong the in vivo half-life of the therapeutic agents (Col. 11, line 32-40). .

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention was made to have motivated Yanagita et al. to couple the polypeptide therapeutic agent with IgG Fc protein to improve the effectiveness of the treatment. One ordinary artisan in the field would have been coupled the polypeptide with IgG Fc in order to take the advantage of prolonging the life of the therapeutic agents within the body for longer and more effective combating the target disease.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitamura et al. (Biochem Biophys Res Commu. 1993 Vol. 194, page 720-725) in view of Goodwin et al..

Kitamura et al. teach an isolated polypeptide having 185 amino aicd residues which encompasses the recited *SEQ ID No. 4* (27/185) and *SEQ ID No. 6* (14/185). However, Kitamura et al. do not explicitly teach fusing the polypeptide with a IgG Fc polypeptide.

As discussed above, Goodwinet al. reference teaches fusing targeted polypeptide with a IgG Fc to improve isolation efficiency. It would have been prima facie obvious to one ordinary skill in the art at the time the invention was made to have motivated Kitamura et al. to couple the polypeptide with IgG Fc to take the advantage of improved isolation yield.

Response to Applicant's Arguments

7. Applicant's arguments with respect to claim 8 have been considered but are moot in view of the new ground(s) of rejection.

8. Note, Applicant argues that none of the reference, i.e. Yanagita (I-II), Layton, Bridon and Kitamura et al. disclose the feature of fusing the target polypeptide with IgG Fc protein. Examiner considers the arguments are persuasive. Therefore, the secondary reference of Layton

et al. is therefore withdrawn. Nevertheless, the new references of Kimberly and Goodwin et al. provide the motivation and suggestion to couple the target polypeptide with IgG Fc for prolonging half-life of therapeutics and increasing the isolation efficiency.

Conclusion

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Examiner, Art Unit 1641

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641